

**Remarks**

This Amendment is in response to the Office Action dated **July 13, 2007**, reopening prosecution after Appeal.

**Interview Summary Record**

In reviewing the file, it appeared that the Examiner might possibly not have recognized that the amendments filed 31 Jan 2006, which had been refused entry in the 2/14/2006 Advisory Action, were represented in the 22 March 2006 reply. This was expressly disclosed in the 22 March 2006 reply but the amendments were shown as "previously presented" and without underlining because applicant was specifically challenging the propriety of the Final status of the outstanding rejection in that reply. The applicant believed (and continues to believe) that entry of the 31 Jan 2006 amendments was a matter of right under the USPTO regulations and so the 22 March 2006 reply properly identified those claims as "previously presented."

When the 22 March 2006 reply was entered (Advisory Action , 04/22/2006) the applicant believed that the Examiner had recognized that the refusal to enter the 31 Jan 2006 amendment was not proper and was entering the amendments to effectively moot the procedural error of the Final Rejection. Relying on that understanding, the applicant filed its Appeal and listed the claims in the Appeal Brief in the form as originally presented on 31 Jan 2006 and represented in the 22 March 2006 reply.

On Sept 7, 2007, the undersigned called Examiner T. Tran to try to clarify the issue of whether the Examiner considered the claims to be different from the recitation in the Appeal Brief.

In the Sept 7, 2007 telephone interview the undersigned explained the sequence of post-final actions in the file. Examiner Tran indicated she thought she had made a mistake in

entering the 22 March 2006 reply and that the paper "violated" patent office regulations in not the underlining the resubmitted changes. This assuredly was not the intention of the undersigned or the Applicant, and the Examiner was told this.

In the course of the Sept 7, 2007 interview the Examiner stated that in formulating the current rejection she considered the language to be as stated in the Appeal Brief. Applicant agrees.

## **Claims Status**

On the basis of the Examiner's statement the claims herein start from the form as listed in the Appeal Brief. So there is no further questioning of the Applicants' disclosure regarding those claims please note specifically that the Appeal Brief claims differ from the claims as they stood on 12/27/2005, the date of the previous final rejection, in the following respects:

<u>Claim</u>	<u>Change</u>
1	Inserted "said coupling agent being selected from the group consisting of polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates."
9	Cancelled.
12	Written in independent form.
30-38	Cancelled.
39-40	Dependency changed to claim 41.
40	Dependency changed to 41.
41	Written in independent form.
43	Changed ", in the tie layer, the coupling agent comprises" to "the coupling agent is incorporated into the tie layer material in an amount of about 0.5% or more."

## **Claims Amendments**

Claims 4-6, 8-9 and 39-44 have been cancelled without prejudice. Applicant reserves the right to present claims directed to the cancelled subject matter in a continuing application.

Claim 1 has been amended to add the word "and" has been inserted between the final two subparagraphs.

Claim 3 has been amended to delete "irradiatively" and insert "after formation of the laminate." See original claim 8 and 7:28-8:2.

Claim 10 has been amended to depend from claim 1 rather than previously cancelled claim 9 and to conform to the antecedent language of claim 1.

Without limitation support for the new claims is shown at least at the following

locations:

45	original claim 1; 2:5-14; 3:6-10; 8:9-15
46	3:21-25; 4:29-32
47	3:18-20
48	original claim 10; 3:17-18
49	original claim 10; 3:17-18
50	original claim 22; 5:6-8
51	original claim 22; 5:6-7, 14, 19, 28, 30
52	original 2; 3:16
53	4:14-16; 4:20-21
54	3:31-4:3; 4:20-21
55	original claim 3; original 8; 7:28-9:24
56	original claim 8; original 3; 7:28-9:24
57	original claim 5; 3:31-4:29
58	4:6-9; 4:32-33
59	original claim 25; 6:17-7:27
60	original claim 26; 6:17-7:27
61	original claims 5 and 7, 7:28-29
62	3:21-25; 4:29-32; original claim 3; original 8; 7:28-9:24
63	original claim 1; original claim 22; 2:5-9; 3:6-10; 8:9-15 5:6-7, 14, 19, 28, 30

With respect to the difference in between polymers and polymer materials (compare e.g. claims 1 and 45 with claim 63), applicant notes it has previously agreed that "the polymer" can be taken to encompass different structural grades of polymer made for the same monomer(s). While this is true, the applicant does not agree the same can be done when a particular polymer material has been recited. Typically different structural grades of a given polymer have a characteristic set of physical properties that are not solely derived from the monomer units which make up those polymer grades. Because they have characteristically different properties they are in fact different materials. Consequently when a specific polymer material is recited, subsequent references to that polymer material cannot be met by a characteristically different material.

Claim 63 recites polymers, not polymer materials, for the first and second layers and the polymer of the tie layer material. Support is shown at least at 3:14-16. In contrast claim 1 recites "a tie-layer polymer material obtained by melt modification of one of the first or the second polymer materials" and claim 45 recites "the tie layer being formed from the second of said pair of polymer materials." In these claims the same polymer material is used for one of the first and second layers and to produce the tie layer material, as taught specifically at 2:5-9.

### **Response to Rejection**

The Office Action asserts that the subject matter of claims 1-13 and 39-44 is obvious under 35 USC §103(a) from Wang et al, US 5,195,969, Samuelson et al, US 6,464,683, or Boer et al, US 6,355,358, in view of Shimura et al, US 5,441,488. Reconsideration is requested.

### **Claims 1, 51, 63**

The claims pertain to laminates of three layers. Further in claims 1, 51 and 63 a coupling agent has been incorporated into the tie layer material and that coupling agent is selected from the group consisting of polyepoxides, polyoxazalines, polycarbodiimides, and polyisocyanates. There is no recitation of a polycarboxylic acid in claims 1, 51 or 63.

The Plexar® polymers of Wang are not modified with any of the coupling agents recited in claim 42. An anhydride is not a polyepoxide, polyoxazaline, polycarbodiimide, or polyisocyanate. The Samuelson et al's tie layer materials likewise are not modified with polyepoxides, polyoxazalines, polycarbodiimides, or polyisocyanates. The oligocarboxylic acid of Boer likewise is not a polyepoxide, polyoxazaline, polycarbodiimide, or polyisocyanate.

Shimura describes a water swellable polymer layer bound to a "matric" material. The matric material itself maybe a layer on another material but the water swellable polymer layer is deposited from solution. In some cases the solution also contains a catalyst. To the extent that Shimura arguably describes three layers, the intermediate layer is a layer of "matric" material that contains an acid anhydride polymer. The acid anhydride polymer is likewise not polyepoxide, polyoxazaline, polycarbodiimide, or polyisocyanate.

None of the documents cited discloses a tie layer having incorporated therein a coupling agent as recited in claims 1, 51 or 63. Therefore the the subject matter of these claims is seen to be nonobvious over any combination Wang et al, Samuelson et al, Boer et al, US and Shimura et al, US 5,441,488.

#### **Claims 45-62**

Independent claim 45 recites medical tubing of a catheter or of a parison for a medical balloon comprising a laminate having, a first layer a second layer and a tie-layer therebetween. The tubing as recited in claim 45 is formed by melt coextrusion using a pair of polymer materials of different polymers to produce the three layers, the first layer being formed of one of said pair of polymer materials and the second layer being formed of the second of the pair of polymer materials. The tie layer is formed from the second of said pair of polymer materials by a melt modification thereof to produce a tie-layer material, the melt modification comprising incorporation therein of a coupling agent having functional groups thereon which are reactive in the melt with functional groups on the first of said first and second polymer materials.

In this case the three recited layers are produced from two polymer materials, not merely from two polymers. One of the same materials as the first and second polymer materials is used to produce the tie layer. This allows the fabricator to tailor the bonding properties of the tie

layer to the specific polymer material pair, without engaging in polymer synthesis (or extensive polymer matching) activities. 1: 27-2:2; 2:5-9.

The tie layers of Wang et al and Samuelson et al, like the commercial tie-layer materials described in the background section of the present application, have only a common polymer relationship, not the relationship recited in claim 45 that a common material has been used to prepare tie layer and one of the adjacent layers. Use of three different as taught in materials Wang et al and Samuelson et al does not provide for a tailoring of the bonding properties of the tie-layer to any specific layer material pair.

Boer et al describes laminate materials, used in applications such as fuel lines, tank filler necks, vapor lines, gasoline pump hoses and piping, cooling fluid line, air-conditioning unit lines or fuel lines. See 8:57-67. None of the disclosed applications pertains to a medical device that comes into contact with bodily fluids. None of the applications would lead one to believe the block copolymer used in the tie layer would be suitable for medical device tubing such as catheter tubing or balloon parison. The fluids that are identified by Boer et al ("fuel, solvents, oil or greases" 2:53-54) are not analogous to blood or other bodily fluids encountered by medical catheters and balloons. The skilled person would not be led to employ such a tie-layer material in medical tubing without a specific indication that it would be both effective in a body fluid contact application and bodily compatible. At least for these reasons the skilled person would not look to Boer et al to provide a tie layer composition for an article of medical device tubing as recited in claim 45.

Shimura et al does not pertain to a melt coextrusion of three layers. To the extent a three layer article is described, at least the outer layer of the water swellable polymer is applied from solution, a technique which not analogous to an extrusion from a polymer melt. The

temperature difference between the claimed melt extrusion application and a solution application, together with the reactivity of the components of the Shimura et al solution would preclude a skilled person from looking to Shimura et al when forming a three layer laminate by melt coextrusion. The skilled person would expect that the reactive components of Shimura et al's water swellable polymer would behave differently under melt conditions, that the bond interface would be different between the two types of deposition, and that the bulk physical properties will likely be different due to such factors as differential crystallization between melt and solution derived layers. Consequently for the subject matter of claims 45-62 Shimura et al is clearly non-analogous.

Wang et al, US 5,195,969, Samuelson et al, US 6,464,683, or Boer et al, US 6,355,358, in view of Shimura et al, US 5,441,488 do not lead a skilled person to prepare a medical tubing as recited in claim 45. At least for that reason claims 45-62 are seen to be patentable over the cited art.

#### **Claims 59-60**

Claim 59 depends from claim 45 and further recite that the tie layer material further has incorporated therein "a catalyst for reaction of the coupling agent with functional groups in the second polymer material." Claim 60 depends from claim 59. The Office Action cites Shimura et al as showing a catalyst, but this is in a solution deposited layer, which is non-analogous to a melt extruded layer for at least the reasons given above. Shimura et al does not render the use of a catalyst in a melt extruded tie layer as recited.

The Office Action also asserts that Boer et al's background shows use of a catalyst is in an adhesion promoting layer. A skilled person would not look to Boer et al for forming medical device tubing for there reasons already given. Further, the catalyst in question is taught



for reaction between components of the adhesion promoter to prepare block copolymers, not for catalyzing reaction between a coupling agent and another layer. *See* US 5258213, which is an English language equivalent of EP0509211 according to the EPO database at esp@cenet. Further the tie layer compositions of US 5258213 do not include a coupling agent. Moreover Boer clearly considers the use of such catalysts to be disadvantageous. At least for these reasons it is not seen how Boer can be taken as suggesting a catalyst for an interlayer reaction in a tie layer of a medical tubing segment that has a coupling agent incorporated therein, as recited in claims 59-60.

**Claims 46 and 62**

These claims recite that the melt modification produced a substantial degradation of the molecular weight of the first polymer material used to prepare the tie-layer material.

The application teaches that molecular weight degradation can accompany an improvement in adhesion (3:21-25; 5:2-5). This is not obvious from any of the cited art. In general extrusion conditions are operated to minimize molecular weight degradation so the skilled person would not be motivated to extrude a substantially degraded material in the absence of an explicit teaching to do so. Nothing in the cited art suggests to prepare a tie-layer in a way that produces a substantial molecular weight degradation of a polymer component thereof.

At least for this additional reason claims 46 and 62 are not obvious from any combination of the cited Wang et al, Samuelson et al, Boer et al, and Shimura et al patents.

**Claims 3, 55, 56 and 62**

Claims 3, 55, 56 and 62 recite that the tie layer polymer, or at least a portion of the tie layer polymer and the first layer polymer, has been crosslinked after formation of the laminate.

The application teaches that the crosslinking will build a secondary network which builds

cohesive strength of the tie layer and can further integrate the tie layer with the adjacent layer corresponding to the first layer of claim 45 (see 8:29-9:10). This network is structurally different than would be obtained by crosslinking a component of a tie layer before extrusion.

Increasing cohesive strength of the tie layer is particularly advantageous in the particular case of claim 62 where polymer molecular weight has been substantially degraded in the tie layer material. The resulting tie layer has high adhesion and cohesion.

At least for the reason that the cited documents do not show crosslinking of a tie layer claims 3, 55, 56 and 62 are not obvious from any combination of the cited Wang et al, Samuelson et al, Boer et al, and Shimura et al patents.

### **Conclusion**

For at least the reasons given above the outstanding rejections are seen to have been overcome. The application is believed to be in condition for allowance. Early and favorable action thereon is respectfully requested.

Respectfully submitted,  
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